510(k) Summary

per 21CFR807.92

JUL 2 6 2012

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DATE PREPARED: June 14, 2012

TRADE OR PROPRIETARY NAME: NERVEVISION SOFTWARE SYSTEMS

CLASSIFICATION NAME: System, Image Processing, Radiological

PREDICATE DEVICE: K111311, Segasist Prostate Auto-Contouring Software

DEVICE DESCRIPTION: The NERVEVISION SOFTWARE SYSTEMS is a software application that has been designed and developed to assist clinicians (radiologists, neurologists, medical physicists, and surgeons) in viewing magnetic resonance images. The software is capable of showing the tissue in individual images from standard Magnetic Resonance (MR) studies for axial, sagittal, or coronal views. The segmented analyses and 3D views of the anatomy can also be viewed.

The NERVEVISION SOFTWARE SYSTEMS provides clinicians with tools to efficiently contour or delineate nerve anatomy in volume data. The results can be saved in digital imaging and communications in medicine (DICOM) and bitmap image file (BMP) formats. The clinician has the ability to save the masked, marked images directly or import them to other software. NERVEVISION SOFTWARE SYSTEMS offers features including:

- Import and export of DICOM images,
- Saving outlines and contours in DICOM or BMP format,
- Semi-automated segmentation,
- Volume segmentation, visualization, and measurement,
- Edge enhancement (contour enhancement by user controlled edge snapping),
- Standard functionalities for image visualization (adjusting contrast & brightness, zoom, and panning)
- Advanced functions of contour editing for manual segmentation (drawing, outlining, inflating, deflating, shifting, cutting and adding to images), and
- User access to modify the segmentation results at any time.

The clinician retains the ultimate responsibility for making the diagnosis and patient management decisions based on the standard practices, and comparisons to individual

images. The NERVEVISION SOFTWARE SYSTEMS is a set of software tools to complement manual (individual image) nerve viewing techniques.

The NERVEVISION SOFTWARE SYSTEMS does not create original input images of nerves, nor does it change the final results obtained once approved and saved by the clinical expert. As such, this software is considered to have a moderate level of concern.

INTENDED USE: The NERVEVISION SOFTWARE SYSTEMS is a stand-alone software application to assist clinicians in segmenting and visualizing nerve anatomy from magnetic resonance images.

TECHNOLOGICAL CHARACTERISTICS: The NERVEVISION SOFTWARE SYSTEMS is a stand-alone software application to be used on personal computers running Windows® operating systems. The software is used to visualize and analyze Magnetic Resonance (MR) images of nerves. The NERVEVISION SOFTWARE SYSTEMS provides visualization of the nerves in both two-dimensions (2D) and three dimensions (3D).

Such PACS devices are considered to be of moderate level of concern to the FDA.

COMPARISONS TO PREDICATE: We believe the NERVEVISION SOFTWARE SYSTEMS is substantially equivalent to the Segasist Prostate Auto-Contouring Software (K111311), which also is a software package for analyzing anatomy from medical images. Both the NERVEVISION SOFTWARE SYSTEMS and the predicate Segasist Software are image analysis tools for anatomy.

The predicate Segasist software can be used with Computed Tomography (CT) and ultrasound images in addition to Magnetic Resonance (MR) images. The NERVEVISION SOFTWARE SYSTEMS are only suited to MR images.

The predicate Segasist software is designed for prostate gland anatomy and the NERVEVISION SOFTWARE SYSTEMS is designed for use with nerve anatomy.

The predicate Segasist software does not perform segmentation of nerves or 3D reconstructions of anatomy, unlike the NERVEVISION SOFTWARE SYSTEMS.

SUBSTANTIAL EQUIVALENCE TESTING: Bench testing was performed to ensure that the software requirements were achieved and validated. The NERVEVISION SOFTWARE SYSTEMS conform to these FDA recognized standards for medical images:

- IEC/ISO 10918-1:1994 Technical Corrigendum 1:2005 Information technology -- Digital compression and coding, and
- NEMA PS 3.1 - 3.18 (2009) Digital Imaging and Communications in Medicine (DICOM) Set.

No clinical tests were performed in the development of the NERVEVISION SOFTWARE SYSTEMS.

The NERVEVISION SOFTWARE SYSTEMS was not evaluated for biocompatibility because no part of this software device is used for patient contact.

We believe that the performance data provided herein support the safety and effectiveness of use of NERVEVISION SOFTWARE SYSTEMS in imaging and examining nerve anatomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

3D Imaging Partners Inc.
% Ms. Carolyn Primus
Consultant
Primus Consulting
7046 Owl's Nest Terrace
BRADENTON FL 34203

Re: K121075
Trade/Device Name: NERVEVISION Software Systems
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 23, 2012
Received: June 28, 2012

Dear Ms. Primus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121075

Indications for Use

510(k) Number (if known): K121075

Device Name: NERVEVISION SOFTWARE SYSTEMS

Indications For Use: The NERVEVISION SOFTWARE SYSTEMS is a stand-alone software application to assist clinicians in segmenting and visualizing nerve anatomy from magnetic resonance images.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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